

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims

1. (Original) A sustained release solid formulation characterized by comprising protein drug, sulfated polysaccharide, and hydrophobic material, wherein the mixture of protein and sulfated polysaccharide are encapsulated with hydrophobic material.

2. (Original) The formulation of claim 1 wherein said sulfated polysaccharide is selected from the group of dextran sulfate, chondroitin sulfate, dermatan sulfate, heparin, heparan sulfate, and keratan sulfate.

3. (Original) The formulation of claim 1 wherein said hydrophobic material is selected from the group of fatty acids, pamoic acid, monoacyl glycerols, sorbitan fatty acid esters, diacyl glycerols, triglycerides, phospholipids, sphingosines, sphingolipids, waxes, and salts or derivatives thereof.

4. (Original) The formulation of claim 1 wherein said sulfated polysaccharide is present in an amount of from 0.01 to 95% weight of the formulation.

5. (Original) The formulation of claim 1 wherein the composition further comprises protein stabilizers.

6. (Original) The formulation of claim 5 wherein said protein stabilizer is selected from the group of sucrose, trehalose, maltose, mannitol, lactose, mannose, polyol, dextran, polyethyleneglycol, cyclodextrin, polyvinylalcohol, hydroxypropylmethylcellulose, hydroxyethylcellulose, polyethyleneimine, polyvinylpyrrolidone, gelatin, collagen, albumin, surfactants, amino acids, inorganic salts, and mixtures thereof.

7. (Currently Amended) A process to prepare a sustained release solid formulation protein drug characterized by comprising a step to prepare a mixture of proteins and sulfated polysaccharides, a step to suspend the mixture obtained in the solution a solution containing hydrophobic materials, and a step to remove the solvent a solvent from the suspension to obtain a solid formulation protein drug.

8. (Original) The process of claim 7 wherein said sulfated polysaccharide is selected from dextran sulfate, chondroitin sulfate, dermatan sulfate, heparin, heparan sulfate, and keratan sulfate.

9. (Original) The process of claim 7 wherein said hydrophobic material is selected from the group consisting of fatty acids, pamoic acid, monoacyl glycerols, sorbitan fatty acid esters, diacyl glycerols, triglycerides, phospholipids, sphingosines, sphingolipids, waxes, and salts or derivatives thereof.

10. (Original) The process of claim 7 wherein said sulfated polysaccharide is present in an amount of from 0.01 to 95% weight of the formulation.

11. (Original) The process of claim 7 wherein the mixture of protein and sulfated polysaccharide is a solid microparticulate form.

12. (Original) The process of claim 11 wherein said solid microparticulate is prepared by drying the liquid mixture of protein and sulfated polysaccharide.

13. (Original) The process of claim 12 wherein said solid microparticulate is obtained by spray drying, freeze drying, spray freeze drying, and drying using supercritical fluid.

14. (Original) The process of claim 7 wherein the mixture of protein and sulfated polysaccharide is a liquid state.

15. (Previously Presented) The process of claim 7 wherein the pH of the mixture of protein and sulfated polysaccharide is lower than the isoelectric point of the protein.

16. (Original) The process of claim 7 wherein the process further comprises a step to add protein stabilizers.

17. (Original) The process of claim 16 wherein said protein stabilizer is selected from the group of sucrose, trehalose, maltose, mannitol, lactose, mannose, polyol, dextran, polyethyleneglycol, cyclodextrin, polyvinylalcohol, hydroxypropylmethylcellulose, hydroxyethylcellulose, polyethyleneimine, polyvinylpyrrolidone, gelatin, collagen, albumin, surfactants, amino acids, inorganic salts, and mixtures thereof.

18. (Previously Presented) The process of claim 11 wherein the pH of the mixture of protein and sulfated polysaccharide is lower than the isoelectric point of the protein.

19. (Previously Presented) The process of claim 14 wherein the pH of the mixture of protein and sulfated polysaccharide is lower than the isoelectric point of the protein.